

Standard Operating Procedure

Title: Functional Testing Guide for Computerised System

- Hard copy report data accurately reflects its source data.
- Pass/Fail signals from interfacing computerised systems and sensors are processed correctly, e.g. accurately rejecting the failed unit of product.
- Correct operation and indexing is maintained after cycle stop, emergency stop, and safety guard being opened.
- Sensor signals for adverse conditions are responded to appropriately, e.g. jam-ups, label outages, etc.
- Data is displayed accurately at operational screen displays and user interfaces.

2.2.2. Boundary Tests

Boundary Testing is used to challenge the specification limits of custom programs and of user-defined configurations. Maximum and minimum values are to be tested in critical input and output fields.

2.2.3. Alarm Tests

Alarm conditions are tested to verify that:

- Entry of invalid data causes an appropriate error message to be displayed.
- Invalid, illegal or adverse conditions such as alarms, errors and hardware failures are identified and highlighted to the user in a way that allows appropriate response.

2.2.4. Error Tests

Error tests (sometimes called negative tests) examine responses to specifically selected invalid inputs or operations, and calculations based on this data. Conditions that are expected to cause errors are thereby deliberately generated and the system response monitored and documented.

Test conditions might include:

- Detection and recovery from incorrect data entry, (e.g. out of range, mismatch with data type).
- Use of input values that seem likely to cause program errors; e.g., "0", "1", NULL, empty string.
- Attempts to generate calculations with confounding special values e.g. division by zero, square root of a negative value.
- Detection of failure of critical sensors and operational interfaces to other computerised systems, (e.g. checking of operation in both ON and OFF state; secondary 'Healthy' inputs; response to the connection being severed mid-operation).

2.2.5. Configuration Tests

Confirm that the validated status is defined, tested and documented for Recipes, (user-defined GAMP 4 configuration files, such as for files containing operating parameters and sequences, vision models, autoclave cycles etc.). These are subject to version control, back-up and archiving procedures. It also confirms that there are appropriate SOP's to define their use and updating; and that any recovered files are the validated versions.

Note: This is different from system configurations, which are normally defined in Installation Qualification.

2.2.6. Stress Test

The aim of Stress Testing is to detect any problems when the system is pushed to its performance limits, and to establish a performance baseline. Test Cases need to be designed to simulate the maximum projected load and over. Functions that require significant time to complete, involve large amounts of data, or include complex processing will be selected for testing. An attempt to identify any compatibility or interference issues with other applications on the server is also beneficial.

2.2.7. Security Tests